MARK RUTKIEWICZ

OBJECTIVE

To take a medical device organization to the next level of product development excellence. To use my vision and hands on leadership to drive best practices in project and operations management. Change processes, tools and culture to reduce product development times and reduce overhead resources.

EXPERIENCE

2004–Present Cardiac Science Inc. Minneapolis, MN

Quality Assurance Director

- Implementing a complete paper to electronic documentation conversion. Implementing a rewrite of all Quality System processes.
- Responsible for Quality, Reliability, Customer Service, Documentation, Equipment Maintenance and Calibration activities.
- Quality System Management representative.
- Report to the COO.

Manage Engineers, Customer Service Analysts, Designers, Software Developers, Technical Writers, Consultants and Configuration Specialists.

2000–2004 St Croix Medical Minneapolis, MN

Product Assurance Senior Director

- Cut product development lifecycle time in half by implementing corporate-wide integrated information management tools, processes and procedures, while maintaining all FDA and European regulatory required information. Received FDA IDE approval 27 days after testing completion.
- Responsible for Operations, OEM and Continuation Engineering, Quality, Reliability, Documentation, Labeling, Equipment Maintenance and Calibration, Patent, Reimbursement and Regulatory Affairs activities.
- Developed Quality Systems that have passed FDA and ISO 13485 audits. Quality System Management representative.
- Report to the CEO.
- Improved documentation throughput from hours to minutes.
- Licensed our Quality system processes and procedures.
- Manage Engineers, Analysts, Designers, Software Developers, Technical Writers, Consultants and Configuration Specialists.

1997–2000 Guidant Corporation St Paul, MN

Project Development Service Manager

- Reduced product development lifecycle time by 20% and documentation errors were reduced by 50%, by implementing my integrated information management processes and while maintaining all FDA and European regulatory required documentation.

- Managed 88 drafters, technical writers and configuration specialists. Consolidated documentation resources across the division and expanded information management support from design and manufacturing to the entire company.
- Reduced turnover from 20% to 3%.
- Implemented on-line tools, processes and procedures to increase compliance and reuse while reducing project development time.
- Created Manufacturing Online, including website, hardware, tools, documents and processes which reduced manufacturing documentation errors by more than 50%.
- Launched the Guidant-wide Intranet.

1994-1996 Guidant Corporation St Paul, MN
Compliance Manager

- Created the Compliance department, plan and processes.
- Implemented compliance system engineering, which led to Guidant Cardiac Rhythm Management group getting only one 483 observation in 30 FDA audits.
- Implemented on-line policy and procedures system.
- Created the Guidant ethics manual.

1987–1994 Cardiac Pacemakers Inc. St Paul, MN
Pulsar/Discovery Pacemaker Development Core Team Member
Senior Manufacturing Engineer
Senior Component Engineer

1984–1987 Control Data, Govt. Systems Bloomington, MN
Component Engineer
Reliability Engineer

EDUCATION

- --------- University of Minnesota Minneapolis, MN
  Bachelor of Electrical Engineering
- --- Professional Engineer License MN
- --- Hamline University St Paul, MN
  Masters of Applied Liberal Studies, Business and Leadership Focus

Continuing Education Courses:

- Configuration Management (CMII) Certification ---
- Dale Carnegie Human Relations Course ---
- University of Minnesota: Eng Cost Accounting, Project Management, Digital Computer Systems
- Company Sponsored: Effective Communications, Weibull, ASIC Reliability, Analog MOS Design, Interpersonal, Team Leader & Facilitator, Computer Design, Semiconductor Mfg, Reliability Testing

CONFERENCES, COMMITTEES AND PUBLISHED PAPERS

- 2004 Med Edge Conference/Medical Alley Mpls, MN
  Effectively Integrating Risk Management into Product Developement

- 2002-2004 Grand Ave Software: Industry Advisory Committee
- 2002 Agile User Conference Presentation Las Vegas, NV
  Innovation and Compliance: The Yin and Yang of Medical Device NPI
- 2002 Agile Conference Presentation Stuttgart, Germany
  Creating a Quality System Architecture in Agile
- 2000 CM II Conference Minneapolis, MN
  Simple and Compliant: Implementing CMII in a High-Tech Start-Up
- 1996 Biomedical Focus Presentation Minneapolis, MN
  Developing a Corporate Compliance Program
- 1991 ASQC Paper and Presentation Milwaukee, WI
  Qualifying Implantable High Voltage Hybrids

REFERENCES

Proprietary information deleted.

CONSULTING

Provided Integrated Information Management consulting to::

- Avail
- Biomec
- Cameron Health
- CVRX
- Data Sciences (Somatech)
- Gilead Pharmaceutical
- Guidant
- Hil-Rom
- Integral Technology
- Johnson and Johnson - Depuy
- Lake Region
- Medtronic
- Omnitract Surgical
- Peak industries
- Pemstar
- Possis
- Sonosite
- Synovis
- VISX